

CLAIMS

1. An intragastric balloon assembly for reducing the food intake of a person suffering from obesity, the intragastric balloon assembly comprising:

a balloon made of an acid resistant distensible material;

an inflating catheter joined at one end to the balloon and configured to inflate the balloon;

a rigid support including an elongated element formed unitarily with the balloon and having a diameter that is larger at an end joined to the balloon and becomes smaller towards an opposing end, said rigid support being configured for use as a guideline and tractor to introduce the balloon into a stomach through a mouth and as a support to maintain the balloon in a substantially fixed position, said rigid support having a groove along a length of the rigid support from the end joined to the balloon and extending up to approximately 15 cm from the end joined to the balloon;

a handle disposed at the opposing end of the rigid support and formed unitarily with the rigid support to permit said rigid support to be held during surgery;

said inflating catheter being fixedly joined at one end to the balloon proximate the rigid support and housed along at least a portion of the length of the inflating catheter within the groove of the rigid support, and configured to be carried along with the rigid support when the assembly is introduced into the stomach and to be detachable from the rigid support for fixation;

an inflating valve configured to at least one of inflate and deflate the balloon that is joined to the inflating catheter and that has at least two flanges for fixation; and

a fixing plate having a first hole with a circular flange formed therein which is configured to adjust and fix the rigid support, a second hole that receives the inflating catheter, and a plurality of fixation holes configured to join the plate by at least one of suture stitches and staples to abdominal tissue.

2. An intragastric balloon assembly according to claim 1, wherein the capacity of the balloon is about 200 to 1000 c.c.

3. An intragastric balloon assembly according to claim 1, wherein the balloon has a substantially circular shape.

4. An intragastric balloon assembly according to claim 1, wherein the balloon has a substantially bilobate shape.

5. An intragastric balloon assembly according to claim 1, wherein the balloon has a substantially kidney shape.

6. An intragastric balloon assembly according to claim 1, wherein the rigid support is made of silicone.

7. An intragastric balloon assembly according to claim 1, wherein the inflating catheter has diameter of about 1.5 to 2.0 mm and a length of approximately 20 cm.

8. An intragastric balloon assembly according to claim 1, wherein the fixing plate has a thickness of approximately 1.5 mm, and is made of at least one of silicone and inert plastic of higher hardness.

9. An intragastric balloon assembly according to claim 1, wherein the fixing plate has a shape selected from circular, ovoid and squared.

10. An intragastric balloon assembly according to claim 1, wherein the fixing plate and inflating valve are disposed in a single integrated plate.

11. An intragastric balloon assembly according to claim 10, wherein the integrated fixing plate has the circular flange and the inflating valve contiguously disposed thereon, so that the inflating catheter can be fixed by an inferior side of the fixing plate to the inflating valve and the rigid support can be passed through the hole and fixed to the circular flange.

12. An intragastric balloon assembly according to claim 10, wherein the integrated fixing plate has the inflating valve, the first hole, and a tubular element disposed at the center of the inflating valve, so that the rigid support can be passed through said tubular element; and the flange on an upper side of the inflating valve to suture and fix the rigid support under tension

13. An intragastric balloon assembly according to claim 1, wherein the rigid support and the balloon are partially covered by a layer of a material configured to promote fibrosis and cicatrisation in regions that will contact tissues.

14. An intragastric balloon assembly according to claim 13, wherein the fibrosis and cicatrisation promoting material is selected from goretex and mersilene.

15. An intragastric balloon assembly according to claim 1, further comprising a circular reinforcement disposed adjacent to a base of the balloon where the rigid support emerges, integrally formed with the balloon and having a plurality of embossments formed thereon radially distributed on an edge thereof, said circular reinforcement being configured to be adhered to an inner wall of the stomach, when setting the balloon assembly in place, to seal a hole formed therein.

16. An intragastric balloon assembly according to claim 15, wherein the circular reinforcement is made of the same material as the balloon.

17. An intragastric balloon assembly according to claim 15, further comprising a foldable plastic screen disposed around the rigid support and spaced apart from the balloon, and integrally formed with the rigid support, said foldable plastic screen being capable of being initially in a folded position, before inserting the balloon assembly into the stomach, and capable of being spread out after crossing the stomach wall, said screen being configured to lay over a stomach external wall and attach thereon to seal an area of the hole formed in the stomach to prevent gastric juices from leaking.

18. An intragastric balloon assembly according to claim 17, wherein the foldable plastic screen is made of silicon.

19. A surgical procedure to set the intragastric balloon of claim 1 to treat a patient suffering from obesity, comprising the steps of:

- applying asepsis and antisepsis measures;
- anesthetizing the patient under an anesthesiologist surveillance;
- placing the patient in a ventral decubitus position;
- performing an abdomen antisepsis;
- setting sterile fields to limit superior hemiabdomen;

introducing a central view flexible endoscope through a mouth of the patient;
identifying the stomach inflated with air by means of the endoscope;
pressing the bottom of a gastric body against the major curvature with the endoscope, to identify a puncture site by locating light through the abdominal wall;
applying local anesthesia with diluted xilocaine without epinephrine at a puncturing site;
making a small incision with a 2 mm knife;
introducing a puncturing trocar at the puncturing site, by piercing all layers of the abdominal wall and perforating the stomach, watching this operation through the endoscope ;
removing a pointed mandrin from trocar ;
introducing into the stomach a resistant suture through the light of trocar ;
taking the suture with the pliers of an endoscope and taking away the endoscope together with the suture through the mouth;
tying the suture to the handle of the rigid support;
making traction of the suture through the abdominal wall so that rigid support along with the catheter and the balloon are carried throughout the digestive tube to the stomach, the rigid support and inflating catheter being taken through the gastric wall and the abdominal wall;
removing the percutaneous trocar;
carrying out a surgical incision of 5-7 cm;
cutting the skin and cellular tissue up to the aponeurosis;
dissecting aponeurosis surface to place the fixing plate on this site;
separating the inflating catheter from the rigid support and cutting the a tip of the rigid support;
inflating the balloon with a fluid;
making traction of the rigid support for the balloon to be attached to the gastric wall and the gastric wall in turn to be adhered to abdominal wall at the peritoneal layer to avoid leakage of gastric content towards the abdominal wall;
fixing the rigid support and introducing it through the first hole , cutting excess of the rigid support and fixing it to the flange by a suture;

fixing the inflating catheter by passing it through a hole of fixing plate, close to the level of the plate flange; cutting the inflating catheter and connecting the inflating catheter to the inflating valve;

fixing the fixing plate to the anterior aponeurosis of the abdomen by suture through fixing holes ;

setting the inflating valve in adjoining way to the incision, perforating the cellular tissue at a distance of 5-6 cm from outside and fixing it to the aponeurosis with suture and;

closing the subcutaneous cellular tissue and the skin.

20. A surgical procedure according to claim 19 including the step of applying a layer of a material promoting fibrosis and cicatrisation over rigid support and the balloon on the regions having contact with the tissues, once they have been taken to the stomach of the patient.

21. A surgical procedure according to claim 19 including the steps of: spreading out the foldable screen once the area of rigid support bearing screen has crossed the stomach wall, so that said screen lays over the stomach external wall and is attached thereon sealing the area of the hole formed in the stomach to prevent gastric juices from leaking.

22. An intragastric balloon assembly for reducing the food intake of a person suffering from obesity, in the intragastric balloon assembly comprising:

a balloon made of an acid resistant distensible material;

an inflating catheter joinable at one end to the balloon and configured to inflate the balloon;

a rigid support included an elongated element formed unitarily with the balloon and having a diameter that is larger at an end joined to the balloon and becomes smaller towards an opposing end, said rigid support being configured for use as a guideline and tractor to take the balloon into a stomach through a mouth and as a support to maintain the balloon in a substantially fixed position, said rigid support having a handle disposed at the opposing end of the rigid support and formed unitarily with the rigid support to permit said rigid support to be held during surgery;

said inflating catheter being detachably joined to the balloon to permit the inflating catheter to be detached from the balloon after inflating;
an inflating valve disposed at a point distant from the rigid support, fixedly attached to the balloon, and connected with detachable catheter for an initial inflating of the balloon; and
a fixing plate having a first hole with a circular flange configured to adjust and fix the rigid support and a plurality of fixation holes to join plate to abdominal tissue.

23. An intragastric balloon assembly according to claim 22, wherein the capacity of the balloon is about 200 to 1000 c.c.

24. An intragastric balloon assembly according to claim 22, wherein the balloon has a substantially circular shape.

25. An intragastric balloon assembly according to claim 22, wherein the balloon has a substantially bilobated shape.

26. An intragastric balloon assembly according to claim 22, wherein the balloon has a substantially kidney shape.

27. An intragastric balloon assembly according to claim 22, wherein the rigid support is made of silicone.

28. An intragastric balloon assembly according to claim 22, wherein the inflating catheter has diameter of about 1.5 to 2.0 mm and a length of approximately 20 cm.

29. An intragastric balloon assembly according to claim 22, wherein the fixing plate has a thickness of approximately 1.5 mm, and is made of at least one of silicone and inert plastic of higher hardness.

30. An intragastric balloon assembly according to claim 22, wherein the fixing plate has a shape selected from circular, ovoid and squared.

31. An intragastric balloon assembly according to claim 22, wherein the inflating valve is disposed in a point diametrically opposed to the rigid support.

32. An intragastric balloon assembly according to claim 22, wherein the rigid support and the balloon are partially covered by a layer of a material configured to promote fibrosis and cicatrisation in regions that will contact tissues.

33. An intragastric balloon assembly according to claim 32, wherein the fibrosis and cicatrisation promoting material is selected from goretex and mersilene.

34. An intragastric balloon assembly according to claim 22, further comprising a circular reinforcement disposed adjacent to a base of the balloon where the rigid support emerges, integrally formed with the balloon and having a plurality of embossments formed thereon radially distributed on an edge thereof, said circular reinforcement being configured to be adhered to an inner wall of the stomach, when setting the balloon assembly in place, to seal a hole formed therein.

35. An intragastric balloon assembly according to claim 34, wherein the circular reinforcement is made of the same material as the balloon.

36. An intragastric balloon assembly according to claim 34, further comprising a foldable plastic screen, disposed around the rigid support and spaced apart from the balloon, and integrally formed with the rigid support, said foldable plastic screen being capable of being initially in a folded position, before inserting the balloon assembly into the stomach, and capable of being spread out after crossing the stomach wall, said screen being configured to lay over a stomach external wall and attach thereon to seal an area of the hole formed in the stomach to prevent gastric juices from leaking.

37. An intragastric balloon assembly according to claim 36, wherein the foldable plastic screen, is made of silicon.

38. A procedure to set the intragastric balloon of claim 22 to treat a patient suffering from obesity, comprising the steps of:

- applying asepsis and antisepsis measures;
- anesthetizing the patient under an anesthesiologist surveillance;
- placing the patient in a ventral decubitus position;
- performing an abdomen antisepsis;

setting sterile fields to limit superior hemiabdomen;
introducing a central view flexible endoscope through a mouth of the patient;
identifying stomach of the patient inflated with air by means of the endoscope;
pressing a bottom of a gastric body against a major curvature with the endoscope, to identify a puncture site by locating light through the abdominal wall;
applying local anesthesia with diluted xilocaine without epinephrine at a puncturing site;
making a small incision with a 2 mm knife;
introducing a puncturing trocar at the puncturing site, by piercing all layers of the abdominal wall and perforating the stomach, watching this operation through the endoscope;
removing a pointed mandrin from trocar;
introducing into the stomach a resistant suture through the light of trocar;
taking the suture with the pliers of an endoscope taking away the endoscope together with the suture through the mouth;
tying the suture to the handle of the rigid support;
making traction of the suture through the abdominal wall so that the rigid support along with the balloon and catheter are carried throughout a digestive tube to the stomach, the rigid support being taken through the gastric wall and the abdominal wall;
inflating the balloon through detachable catheter that is partially exposed at that time through the patient's mouth to a partial volume of about 200 to 300cc that allows exerting tension between the rigid support and the inflated balloon, so as to close the perforated stomach wall to the parietal peritoneum layer;
separating the inflating catheter from the balloon;
removing percutaneous trocar;
carrying out a surgical incision of 5-7 cm;
cutting the skin and cellular tissue up to the aponeurosis;
dissecting aponeurosis surface to place the fixing plate on this site;
making traction on the rigid support for the balloon to be attached to the gastric wall and the gastric wall in turn to be adhered to abdominal wall at the peritoneal layer to avoid leakage of gastric content to the abdominal wall;

fixing the rigid support and introducing the rigid support through hole, cutting excess of the rigid support and fixing the rigid support to flange by a suture; fixing the fixing plate to the anterior aponeurosis of the abdomen by suture through fixing holes ;
closing the subcutaneous cellular tissue and the skin.

39. A surgical procedure according to claim 38 including the step of applying a layer of a material promoting fibrosis and cicatrisation over the rigid support and the balloon on the regions having contact with the tissues, once they have been taken to the stomach of the patient.

40. A surgical procedure according to claim 38 taken in combination with the intragastric balloon assembly of claims 34 to 37, including the steps of: spreading out the foldable screen once the area of rigid support bearing screen has crossed the stomach wall so that said screen lays over the stomach external wall and is attached thereon sealing the area of the hole formed in the stomach to prevent gastric juices from leaking.